

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA**

GILEAD SCIENCES, INC. and
EMORY UNIVERSITY,

Plaintiffs,

v.

MYLAN INC. and MYLAN
PHARMACEUTICALS INC.,

Defendants.

Civil Action No. 1:14-cv-99 (IMK)

**MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION TO
STRIKE MYLAN'S THIRD SEPARATE DEFENSE**

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I. INTRODUCTION

Plaintiffs Gilead Sciences, Inc. and Emory University (collectively, “Gilead”) respectfully move to strike the Third Separate Defense of Defendants Mylan Inc. and Mylan Pharmaceuticals Inc. (collectively, “Mylan”). That defense, entitled “Unenforceability,” is wholly lacking in even the barest details necessary to afford the Court and Gilead notice of the nature of Mylan’s defense.

First, Mylan’s defense fails to meet even the minimum pleading requirements of Rule 8(b)(1), as articulated by *Twombly-Iqbal*. **Second**, to the extent the defense is based on equitable estoppel or inequitable conduct, it additionally fails to meet the particularity requirements of Rule 9(b). **Third**, to the extent the defense is based on alleged expiration or patent misuse, it is redundant of Mylan’s Fourth Separate Defense (“Expiration”) and Fifth Separate Defense (“Misuse”). Accordingly, the Court should grant Gilead’s motion to strike Mylan’s Third Separate Defense.

II. FACTUAL BACKGROUND

On June 9, 2014, Gilead filed the original Complaint against Mylan, asserting infringement of U.S. Patent Nos. 6,642,245 (the “’245 patent”), 6,703,396 (the “’396 patent”), and 8,592,397 (the “’397 patent”). (D.I. 1.) On January 22, 2015, with the Court’s permission, Gilead filed a Second Amended Complaint adding a claim for infringement of a fourth patent, U.S. Patent No. 8,716,264 (the “’264 patent”). (D.I. 94.) (The ‘245 and ‘396 patents are referred to herein as the “FTC Patents,” and the ‘397 and ‘264 patents are referred to herein as the “FTC/TDF Fixed Dose Combination Patents.”) On February 9, 2015, Mylan filed its Answer, Defenses, and Counterclaims to Gilead’s Second Amended Complaint. (D.I. 97.)

Mylan’s Answer includes a Third Separate Defense, entitled “Unenforceability,” which states in its entirety:

THIRD SEPARATE DEFENSE
(Unenforceability)

100. By virtue of the prosecution proceedings before the United States Patent and Trademark Office of the patent applications leading to the '245, '396, '397, and '264 patents, Plaintiffs are estopped from maintaining that any valid or enforceable claim of the '245, '396, '397, and '264 patents is infringed by the product that is the subject of Mylan's ANDA No. 20-6436.

(D.I. 97, ¶ 100.) Mylan's Answer also includes a Fourth Separate Defense ("Expiration") and a Fifth Separate Defense ("Misuse"). (D.I. 97, ¶¶ 101-43.) Both the Fourth and Fifth Separate Defenses pertain to only the FTC Patents. *See id.*

On February 23, 2015, Mylan served its supplemental response to Gilead's Interrogatory No. 4, which seeks the basis for any contention that any claim of the asserted patents is invalid and/or unenforceable.¹ Declaration of David B. Bassett in Support of Plaintiffs' Motion to Strike Mylan's Third Separate Defense ("Bassett Decl."), Ex. 1 at 6-7. With respect to unenforceability, Mylan's response simply referred Gilead to Mylan's Fourth and Fifth Separate Defenses. *See id.* at 8. Conspicuously absent from Mylan's response was any mention of its Third Separate Defense. *See generally id.* at 6-8.

III. LEGAL STANDARD

Under Rule 12(f), "[a] court may strike from a pleading an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter." Fed. R. Civ. P. 12(f). "Thus, a defense may be excised if it does not meet the pleading requirements of Rules 8 and 9." *Bradshaw v. Hilco Receivables, LLC*, 725 F. Supp. 2d 532, 535 (D. Md. 2010) (citation omitted). The district court enjoys wide discretion in determining whether to strike an affirmative defense under Rule 12(f) "to minimize delay, prejudice and confusion by narrowing the issues for

¹ In accordance with the scheduling order in the case, Gilead has previously disclosed to Mylan the claims of the patents it intends to assert, based on the discovery and information presently available to it.

discovery and trial.” *Id.* (internal quotation marks omitted).

“The majority of district courts, including those within [the Fourth] [C]ircuit, have concluded that the *Twombly–Iqbal* approach applies to affirmative defenses.” *Long v. Welch & Rushe, Inc.*, 28 F. Supp. 3d 446, 461-62 (D. Md. 2014). In *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), the Supreme Court held that, to be minimally compliant with the pleading requirements of Rule 8(a)(2), a complaint must set forth “enough factual matter (taken as true) to suggest” a cognizable cause of action. *Id.* at 556. In its subsequent decision in *Ashcroft v. Iqbal*, 556 U.S. 662 (2009), the Supreme Court reiterated that “[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice.” *Id.* at 678-79.

Concluding that the *Twombly–Iqbal* standards also apply to affirmative defenses, courts have recognized that “the interests of consistency and fairness are furthered by holding defendants to the plausibility standard, and plaintiffs are entitled to receive proper notice of defenses in advance of the discovery process and trial.” *Bradshaw*, 725 F. Supp. 2d at 536; *see also Long*, 28 F. Supp. 3d at 462 (adopting the majority view that affirmative defenses must meet the *Twombly* and *Iqbal* standards “because defendants should be held to the same pleading standard as plaintiffs and boilerplate defenses require counsel to conduct unnecessary discovery”); *Palmer v. Oakland Farms, Inc.*, 2010 WL 2605179, at *5 (W.D. Va. June 24, 2010) (“[B]y applying the *Twombly–Iqbal* [sic] heightened pleading standard to affirmative defenses, a plaintiff will not be left to the formal discovery process to find[]out whether the defense exists and may, instead, use the discovery process for its intended purpose of ascertaining the additional facts which support a well-pleaded claim or defense.”) (citation omitted). Application of the *Twombly–Iqbal* standards to defenses will “promote litigation efficiency and will discourage defendants from asserting boilerplate affirmative defenses that are based upon

nothing more than some conjecture that [they] may somehow apply.” *Bradshaw*, 725 F. Supp. 2d at 536 (internal quotation marks omitted).

To meet the *Twombly-Iqbal* standard, therefore, affirmative defenses must be pled in a manner that “ensure[s] that an opposing party receives fair notice of the factual basis for an assertion contained [in a] defense.” *Id.* While this standard “does not require the assertion of all supporting evidentiary facts,” it does require that, “[a]t a minimum, [] some statement of the ultimate facts underlying the defense . . . must be set forth, and both its non-conclusory factual content and the reasonable inferences from that content, must plausibly suggest a cognizable defense available to the defendant.” *Ulyssix Techs., Inc. v. Orbital Network Eng’g, Inc.*, 2011 WL 631145, at *15 (D. Md. Feb.11, 2011) (citation omitted).

Finally, for defenses based in fraud, the Federal Rules imposes an even higher pleading standard, requiring such defenses to be pled with particularity. Fed. R. Civ. P. 9(b) (“In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake.”); *cf. Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1326-27 (Fed. Cir. 2009) (holding that, in pleading inequitable conduct in patent cases, Rule 9(b) requires identification of the specific “who, what, when, where, and how” of the material misrepresentation or omission allegedly committed before the PTO).

IV. MYLAN’S THIRD SEPARATE DEFENSE SHOULD BE STRICKEN

A. Mylan’s Unenforceability Defense Fails to Meet Even the Minimum Pleading Requirements of Rule 8(b)(1), as Articulated by *Twombly-Iqbal*.

As discussed above, Mylan’s Third Separate Defense states in its entirety:

THIRD SEPARATE DEFENSE (Unenforceability)

100. By virtue of the prosecution proceedings before the United States Patent and Trademark Office of the patent applications leading to the ’245, ’396, ’397, and ’264 patents, Plaintiffs are estopped from maintaining that any valid or enforceable claim of

the '245, '396, '397, and '264 patents is infringed by the product that is the subject of Mylan's ANDA No. 20-6436.

(D.I. 97, ¶ 100.) Despite titling its defense “Unenforceability,” Mylan fails to identify the nature of any alleged unenforceability—*e.g.*, equitable estoppel, inequitable conduct, waiver, or laches. The Court and Gilead are therefore unable to determine the elements of the defense that Mylan is required to prove. In addition, Mylan fails to allege any facts plausibly suggesting a cognizable unenforceability defense. Such deficient allegations fall far short of providing the Court and Gilead with fair notice of the grounds upon which Mylan's defense rests. *See Palmer*, 2010 WL 2605179, at *5 (“At a minimum . . . some statement of the ultimate facts underlying the defense must be set forth, and both its non-conclusory factual content and the reasonable inferences from that content, must plausibly suggest a cognizable defense available to the defendant.”).

Moreover, just over a week ago, Mylan served a supplemental response to Gilead's Interrogatory No. 4, which sought the basis for any contention of patent unenforceability. In its response, Mylan simply referred to its Fourth and Fifth Separate Defenses. *See Bassett Decl.*, Ex. 1 at 8. Tellingly, Mylan did not mention—let alone provide any further detail regarding—its Third Separate Defense. *See generally id.* at 6-8. Such an omission emphasizes that there is no meat on the barest-of-bones allegations of Mylan's Third Separate Defense.

This is particularly true for a defense that takes a broad-brush approach to four different patents falling within two entirely separate families. The FTC Patents pertain to the compound emtricitabine itself, while the FTC/TDF Fixed Dose Combination Patents relate to certain combinations of emtricitabine and a different compound, TDF, and methods of using such combinations. The two families are unrelated and share no common inventors. The FTC Patents claim inventions by Emory professors, while the FTC/TDF Fixed Dose Combination Patents claim inventions by Gilead scientists more than a decade later, making Mylan's reference to “the

prosecution proceedings before the United States Patent and Trademark Office” particularly vague and inappropriate. Mylan has certainly articulated no unenforceability theory encompassing all four patents.

Accordingly, the Court should strike Mylan’s Third Separate Defense for failing to meet even the minimum pleading requirements of Rule 8(b)(1). *See, e.g., Alston v. Equifax Info. Servs., LLC*, 2014 WL 580148, at *3 (D. Md. Feb. 11, 2014) (striking affirmative defenses “because they fail[ed] to provide fair notice of the factual basis for the assertions presented”); *Bradshaw*, 725 F. Supp. 2d at 537 (striking affirmative defenses for failing to “contain sufficient factual language needed to impart fair notice to” the plaintiff); *Ulyssix Techs., Inc.*, 2011 WL 631145, at *15-16 (striking affirmative defenses for failing to contain a factual basis and therefore failing to provide fair notice to the plaintiff).

B. To the Extent Mylan’s Unenforceability Defense Is Based on Equitable Estoppel or Inequitable Conduct, It Additionally Fails to Meet the Particularity Requirements of Rule 9(b).

As discussed above, Mylan fails to identify any legal theory of “unenforceability” to enable the Court or Gilead to determine the elements of the defense that Mylan is required to prove. It is thus anyone’s guess on what theory Mylan’s defense is actually based. On the one hand, Mylan states that Gilead is “estopped” from asserting its claims, suggesting a possible (though unarticulated) defense based on equitable estoppel. On the other hand, Mylan vaguely refers to “prosecution proceedings,” perhaps implying a defense based on some (yet unmade) allegation of inequitable conduct. To the extent Mylan’s defense is based on either theory, it fails to satisfy the particularity requirement of Rule 9(b). *See, e.g., Exergen Corp.*, 575 F.3d at 1326 (stating that inequitable conduct must be pled with particularity under Rule 9(b)); *Seaboard Int’l, Inc. v. Cameron Int’l Corp.*, 2013 WL 3936889, at *7 (E.D. Cal. July 30, 2013) (stating that equitable estoppel must be pled with particularity under Rule 9(b)).

To establish equitable estoppel, an alleged infringer must show that: (1) “[t]he patentee, through misleading conduct, leads the alleged infringer to reasonably infer that the patentee does not intend to enforce its patent against the alleged infringer”; (2) “[t]he alleged infringer relies on that conduct”; and (3) “[d]ue to its reliance, the alleged infringer will be materially prejudiced if the patentee is allowed to proceed with its claim.” *A.C. Aukerman Co. v. R.L. Chaides Constr. Co.*, 960 F.2d 1020, 1028 (Fed. Cir. 1992). “Because equitable estoppel involves misleading conduct as one of its elements, a defendant must plead equitable estoppel with particularity under Rule 9(b).” *Seaboard Int’l, Inc.*, 2013 WL 3936889, at *7; *see also Bayer CropSci. AG v. Dow AgroScis. LLC*, 2011 WL 6934557, at *3, *5 (D. Del. Dec. 30, 2011) (stating that equitable estoppel must satisfy Rule 9(b) pleading requirements). “Therefore, [] equitable estoppel [] must be pleaded in detail and provide the who, what, when, where, and how of the alleged misleading conduct.” *Seaboard Int’l, Inc.*, 2013 WL 3936889, at *7 (citing *Exergen*, 575 F.3d at 1327).²

Mylan’s Third Separate Defense includes no allegations as to **any** of the elements of equitable estoppel—*i.e.*, misleading conduct, reliance, and material prejudice—let alone detailed allegations providing the who, what, when, where, and how of any alleged misleading conduct. At most, Mylan refers vaguely to “prosecution proceedings.” Thus, to the extent Mylan’s unenforceability defense is based on equitable estoppel, it does not come even close to meeting the particularity requirements of Rule 9(b). *See, e.g., Bayer CropSci. AG*, 2011 WL 6934557, at *3, *5 (striking equitable estoppel defense for failing to offer the particularity required by Rule 9(b) for claims sounding in fraud); *Sun Microsystems, Inc. v. Versata Enters., Inc.*, 630 F. Supp. 2d 395, 408-09 (D. Del. 2009) (striking equitable estoppel defense for lacking factual detail);

² The Federal Circuit has explained that *Exergen*’s pleading requirements apply to all claims that fall under Rule 9(b), not just inequitable conduct cases. *See In re BP Lubricants USA Inc.*, 637 F.3d 1307, 1311 (Fed. Cir. 2011).

Amgen, Inc. v. F. Hoffman-La Roche Ltd., 480 F. Supp. 2d 462, 470 (D. Mass. 2007) (finding defendants' allegations insufficient to establish an equitable estoppel defense).

Inequitable conduct requires the alleged infringer to prove that “(1) an individual associated with the filing and prosecution of a patent application made an affirmative misrepresentation of a material fact, failed to disclose material information, or submitted false material information; and (2) the individual did so with a specific intent to deceive the PTO.” *Exergen Corp.*, 575 F.3d at 1327 n.3 (citations omitted). Not surprisingly, “in pleading inequitable conduct in patent cases, Rule 9(b) requires identification of the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO.” *Id.* at 1327.

Once again, Mylan includes no allegations as to *any* of the elements of inequitable conduct, let alone detailed allegations providing the who, what, when, where, and how of any alleged material misrepresentation or omission committed before the PTO. The vague reference to “prosecution proceedings” is wholly inadequate to meet the particularity requirements of Rule 9(b). *See, e.g., Senju Pharm. Co. v. Apotex, Inc.*, 921 F. Supp. 2d 297, 308 (D. Del. 2013) (granting motion to strike affirmative defense of unenforceability for inequitable conduct for failure to meet the pleading requirements under *Exergen*); *Mike's Train House, Inc. v. Broadway Ltd. Imports, LLC*, 2011 WL 2415014, at *3-5 (D. Md. June 10, 2011) (same); *Applied Interact, LLC v. Cont'l Airlines, Inc.*, 2008 WL 177740, at *8-9 (E.D. Va. Jan. 17, 2008) (striking inequitable conduct defense because it lacked the specificity and particularity required by Rule 9(b)).

Therefore, to the extent Mylan's unenforceability defense is based on equitable estoppel or inequitable conduct, it should additionally be stricken for failing to meet the particularity requirements of Rule 9(b).

C. To the Extent Mylan's Unenforceability Defense Is Based on Alleged Expiration or Patent Misuse, It Is Redundant of Mylan's Fourth and Fifth Separate Defenses.

As discussed in Part II, *supra*, Mylan's Answer also includes a Fourth Separate Defense, entitled "Expiration," and a Fifth Separate Defense, entitled "Misuse." Both defenses are based on similar factual allegations, relating to the Patent Office's withdrawal of earlier-filed terminal disclaimers relating to the '396 and '245 patents. There is no mention of any of these factual allegations in Mylan's Third Separate Defense of "unenforceability." The ambiguous reference to "prosecution proceedings" certainly provides no information linking Mylan's Third Separate Defense with its Fourth and Fifth Separate Defenses. In responding to a Gilead interrogatory seeking the basis for any contention of patent unenforceability, Mylan simply referred to its Fourth Separate Defense ("Expiration") and Fifth Separate Defense ("Misuse") ***but not its Third Separate Defense ("Unenforceability")***. See Bassett Decl., Ex. 1 at 8. Therefore, although perhaps unlikely given Mylan's pleadings to date, to the extent Mylan's Third Separate Defense is based on the same factual assertions and legal theories that form the basis for its expiration and patent misuse defenses, it should be stricken under Rule 12(f) as redundant of Mylan's Fourth and Fifth Separate Defenses.³ See *Miller v. Fuhu Inc.*, 2014 WL 4748299, at *2 (C.D. Cal. Sept. 22, 2014) (finding that certain affirmative defenses were merely variations on the first affirmative defense and striking them as redundant); *Dacar v. Saybolt LP*, 2010 WL 5634378, at

³ Moreover, to the extent Mylan's unenforceability defense is based on its Fourth and Fifth Separate Defenses (which refer only to the FTC Patents), those have no applicability to the TDF/FTC Fixed Dose Combination Patents. Therefore, at a minimum, the unenforceability defense should be stricken as to the TDF/FTC Fixed Dose Combination Patents.

*2 (E.D.N.C. Aug. 23, 2010) (striking defense, in part, because it was redundant); *Nat'l Presto Indus., Inc. v. Black & Decker (U.S.) Inc.*, 760 F. Supp. 699, 703 (N.D. Ill. 1991) (striking prosecution history estoppel defense as redundant of two other affirmative defenses).

V. CONCLUSION

For the foregoing reasons, Gilead respectfully requests that the Court strike Mylan's Third Separate Defense.

Dated: March 2, 2015

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on March 2, 2015, the foregoing **MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION TO STRIKE MYLAN'S THIRD SEPARATE DEFENSE** was served upon the attorneys of record for Defendants Mylan Inc. and Mylan Pharmaceuticals Inc. using the CM/ECF system, which will send notification of the filing to the counsel of record for Mylan Inc. and Mylan Pharmaceuticals Inc.

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